

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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 )  
 In Re: Levaquin Products )  
 Liability Litigation, ) File No. 08-md-1943  
 ) (JRT/AJB)  
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 )  
 ) Minneapolis, Minnesota  
 ) September 28, 2010  
 ) 10:10 A.M.  
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BEFORE THE **HONORABLE JOHN R. TUNHEIM**  
 UNITED STATES DISTRICT COURT JUDGE  
**(MOTIONS HEARING)**

APPEARANCES

For the Plaintiffs: **RONALD S. GOLDSER, ESQ.**  
**LEWIS J. SAUL, ESQ.**  
**BRIAN McCORMICK, ESQ.**

For the Defendants: **JOHN DAMES, ESQ.**  
**WILLIAM H. ROBINSON, JR., ESQ.**  
**WILLIAM ESSIG, ESQ.**  
**TRACY J. VAN STEENBURGH, ESQ.**

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Proceedings recorded by mechanical stenography;  
 transcript produced by computer.

**10:10 A.M.**

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1 the gallery here, and there are going to be matters that  
2 are -- that have been to date confidential and are  
3 confidential, some documents embedded in the presentation,  
4 and my concern is that we don't wish to waive that. The  
5 motion hasn't yet been decided by the Court.

6 THE COURT: Okay. Very well.

7 MR. GOLDSER: We certainly oppose any action  
8 taken with regard to that. We think this is an open  
9 courtroom. The documents that we're going to be using have  
10 all been used in depositions, and none of the depositions  
11 have been marked as confidential ever, except minor parts  
12 dealing with individual personal finances, so the documents  
13 even though they may have a confidential stamp on them  
14 aren't even confidential anymore.

15 Presumption, strong presumption in favor of an  
16 open courtroom.

17 THE COURT: Let's address that when we get to it.  
18 Let's start with the punitive damages motion.

19 MR. GOLDSER: Okay. Thank you, Your Honor. The  
20 way we will divide up the punitive damages is, my  
21 presentation that is before you is designed to be a bullet  
22 point presentation. These are what we considered to be the  
23 bad acts, all of which have been substantiated by  
24 voluminous filings in the briefs.

25 I will highlight those bad acts for you. I will

1 call your attention to several documents. I am not going  
2 to be going through a lot of documents. The presentation  
3 has a lot of hyperlinks on them. Mr. Essig tells me that  
4 unfortunately the copy I gave to him, the hyperlinks  
5 weren't working. I don't know if that was true of the  
6 Court's copy or not. Obviously I hope they were working.

7 I'm on my laptop. I know they work. At least  
8 they did an hour ago. So we will see where that takes us.  
9 There are a few in particular that I want to call to the  
10 Court's attention. Mr. Saul will follow me on this and  
11 focus on the Ingenix study, although I will cover it fairly  
12 quickly.

13 The whole notion of the punitive damages motion,  
14 to start off with, there are a couple of preliminary legal  
15 issues that I want to address and get out of the way right  
16 away. First, the question of choice of law, that's been  
17 briefed extensively. We think there is little doubt that  
18 Minnesota law applies to this question. Even if it  
19 doesn't, we think we have met the New Jersey standard, and  
20 I'm quite perplexed by the defense posture.

21 To suggest that New Jersey law would apply,  
22 because as federal courts have rejected the *McDarby*  
23 decision out of the New Jersey appellate court, if you  
24 decide that New Jersey law applies and that *McDarby* is no  
25 longer good law in light of *Wyeth*, I think they have just

1 opened themselves up to a whole punitive damages claim in  
2 New Jersey in state court that they don't anticipate. So I  
3 don't think they really want to go there, and I don't think  
4 they're really serious about it.

5 Secondly, the law is quite clear to me that what  
6 you consider on this record is plaintiffs' prima facie  
7 proof that defendant doesn't have the right to  
8 cross-examine it. They don't have the right to challenge  
9 it. They don't have the right to present any of their own  
10 evidence, and so to the extent that the defense wants to  
11 present documents to you today, I don't think you consider  
12 them. I don't think they're part of the prima facie case  
13 at this point.

14 I mean, I'm glad to have had their brief because  
15 I now see what their closing argument is in front of the  
16 jury, and it's very nice, but they don't get to make that  
17 argument today. So for us what matters is what does the  
18 evidence show and what is this case all about, and as a  
19 starting point, the case is about money.

20 And this first slide will show you the history of  
21 the gross revenues that the company has earned over the  
22 years year by year on Levaquin. This is all public  
23 material. It comes from their annual report, so this is  
24 all out in the public domain.

25 So if our story for this motion begins in April

1 of 2001, you can see that starting in 2001 through 2009  
2 we're talking about roughly 13 billion dollars, so what's  
3 at stake here for the company looking forward from 2001  
4 when our story begins is the potential of 13 billion  
5 dollars of lost revenue. That's what they needed to  
6 protect. That was their motive. It was Ortho-McNeil's  
7 number one drug.

8 Their actions were deliberate. The Statute  
9 549.20 says that in order to get punitive damages,  
10 plaintiff must show a deliberate disregard for the rights  
11 and safety of others. As the Court knows, that can be  
12 shown several different ways.

13 One of the ways is to talk about intentional  
14 acts. The other is to talk about deliberate disregard of  
15 knowledge and facts, and you'll see that there were both  
16 that occurred here, much disregard of information that was  
17 out and available.

18 But before I get to those acts, what I want to  
19 talk about is the mindset that the company had, and some of  
20 the early documents that show the mindset I'm going to show  
21 those here. They felt that an adverse regulatory decision  
22 in Europe was going to be devastating. What was that? Let  
23 me tell you the story.

24 It starts in April of 2001, as the brief shows  
25 you, when the European, the French regulators went to

1 Johnson & Johnson's marketing partner Aventis and said  
2 there is an increased reporting of tendon problems,  
3 particularly with Levaquin. And they wanted to know what  
4 that was about, and they wanted to know whether Levaquin  
5 was experiencing a greater tendon disorder report than any  
6 of the other drugs in the class of the fluoroquinolones.

7 So the report started coming to Aventis, and  
8 Aventis immediately contacted Johnson & Johnson, and they  
9 started talking to each other about what would be the  
10 ultimate ramifications of this. So April of 2001 leads to  
11 July 24, 2001.

12 The partners come together at the Kitano Hotel in  
13 New York City. It's a beautiful place. It is located on  
14 37th and Park Avenue, and next time you're in New York you  
15 ought to run by. It's just a gorgeous hotel, and they meet  
16 in board room 301. What is it they're talking about in  
17 board room 301?

18 They are talking not about safety. They are not  
19 talking about health concerns. What they're talking about  
20 is money. They're talking about the devastating potential  
21 of the adverse regulatory decision that might come out of  
22 Europe.

23 Now, who was there for Johnson & Johnson? One  
24 guy that was there was Dr. James Kahn. Dr. Kahn was a  
25 medical affairs guy. He was not a marketer. He was not in

1 sales. He was not in economics. He was the guy who gave  
2 birth to the molecule and gave birth to the science, but  
3 his whole mindset was about marketing and economics.

4 And so as you can see from this first document,  
5 which was used in Dr. Kahn's deposition which was not  
6 marked as confidential, he says, The repercussions from an  
7 adverse regulatory decision in France, who among us can  
8 forget what happened over there to sparfloxacin, would be  
9 immediate and devastating, so let's act promptly.

10 MR. DAMES: I just wanted to object to something,  
11 Your Honor, and I'm sorry, Ron.

12 The document by its own at the bottom says  
13 protected document, document subject to protective order.  
14 However we want to handle this issue, I don't want to fall  
15 pit to his argument again, but we're going to run into  
16 this.

17 THE COURT: Mr. Goldser?

18 MR. GOLDSER: As I said, this is marked as  
19 Plaintiff's MDL Exhibit Number 38. That's also on the  
20 bottom. It's part of Dr. Kahn's deposition. It is part of  
21 Larry Johnson's deposition. Those depositions were not  
22 marked as sealed, and I think counsel will agree to that  
23 fact, and so this document is already in the public domain.

24 You never marked them as confidential, guys.

25 MR. DAMES: We marked the document as

1 confidential, Your Honor. The transcript portions were not  
2 marked confidential, the transcript itself, but the  
3 document itself has been consistently marked confidential.  
4 I just think that once that issue is decided by the Court  
5 as to the confidentiality of those documents, obviously  
6 this will be one way or another resolved, but we did  
7 protect that document.

8 The transcript portions, the testimony, I frankly  
9 don't remember if they were or not, but I will assume that  
10 they were not.

11 THE COURT: They were not made confidential?

12 MR. DAMES: The testimonial portion.

13 MR. ROBINSON: No, Your Honor. The transcripts  
14 were not marked protected or confidential, but under the  
15 protective order, we had the right to mark documents as  
16 confidential. I don't think there is any requirement that  
17 we go back each time a protected document is discussed in a  
18 deposition and seal that part of the deposition. It's not  
19 a public record.

20 MR. GOLDSER: One other item, Your Honor. I read  
21 this very sentence to Dr. Kahn in his deposition. It's  
22 part of the transcript. That's not confidential.

23 THE COURT: Do you have other documents as part  
24 of this presentation that raise this same issue?

25 MR. GOLDSER: Yes. There will be another

1 document, the next one, which is one of the most  
2 significant documents in the case, also authored by  
3 Dr. Kahn, I went through it in copious detail with him, and  
4 I read most of the parts I'm going to read to you in his  
5 deposition. They're part of the transcript.

6 THE COURT: Anything else then besides that?

7 MR. GOLDSER: There will be one or two others.  
8 There is one that I am pretty sure was not used in the  
9 deposition. I can tell you which one that is when I come  
10 to it.

11 THE COURT: Let's address that when we come to  
12 it. Since the language was read in the deposition, which  
13 is open and not marked confidential, I will allow at least  
14 these two documents to go forward.

15 Go ahead.

16 MR. GOLDSER: So let me explain the significance  
17 of that line. It's got two things of import. One is you  
18 can see that the repercussions of an adverse regulatory  
19 decision would be immediate and devastating, so let's act  
20 promptly. It tells you about the mindset of the company as  
21 of July 21, 2005, right after the Kitano meeting.

22 The other thing that it mentions, it says in  
23 parentheses, Who among us can forget what happened over  
24 there to sparfloxacin. Sparfloxacin was another  
25 fluoroquinolone. It had phototoxicity problems. There was

1 a contraindication given to sparfloxacin because of  
2 phototoxicity, and its use was severely restricted.

3 So the reference, and Dr. Kahn explains this in  
4 his deposition is, we can't afford to have a  
5 contraindication to Levaquin because the same thing would  
6 happen to us in Levaquin as what happened -- as happened to  
7 sparfloxacin. Our sales would go down. That 13 billion  
8 dollars I showed you in the first slide was in jeopardy.

9 That's the mindset. That's the deliberate  
10 disregard of patient rights. It was about money, and the  
11 statement comes from the doctor, the safety officer. It's  
12 not coming from the marketing people. What else did they  
13 say? It would have serious implications for marketing.

14 This is the second document that I just described  
15 to you. It is James Kahn's document. It is his long  
16 memorandum that, it is his long memorandum that describes  
17 what happened at the Kitano meeting, and I hope this is  
18 readable enough on your screen. I want to go through a  
19 number of these.

20 These are the quotations that I read to Dr. Kahn  
21 in his deposition. I don't know that I got all of the ones  
22 that I'm about to recite, but many of them, and this  
23 document was certainly included. It was MDL 98. It was  
24 noted that way in Dan Fife's deposition, as well as being  
25 used in Jim Kahn's.

1 Kahn writes that the regulatory situation in  
2 France was a very worrisome regulatory situation. It has  
3 clear and serious implications for our marketing of  
4 Levaquin and could have an impact in the U. S. as early as  
5 the coming respiratory season. I believe this matter to be  
6 urgent and to require our immediate attention.

7 That's the first paragraph. That certainly shows  
8 the mindset of Jim Kahn as he is conveying what happened at  
9 the Kitano meeting, but then if you go down to that third  
10 paragraph, the one that I just blocked off, this has some  
11 particular importance. These data should be considered  
12 against a prevailing background perception that both  
13 ofloxacin and levofloxacin might have greater tendinopathic  
14 potential than other fluoroquinolones.

15 Comparative animal data had previously suggested  
16 that the two agents were more prone to induce lesions than  
17 were many other members of the class. Reporting rates for  
18 ofloxacin, ofloxacin related tendinopathies have  
19 traditionally been higher than for other FQ fluoroquinolone  
20 agents. In our U. S. post marketing Levaquin experience,  
21 we see has a higher reporting rate for tendon disorders  
22 than for virtually any other AE, adverse event, commonly  
23 regarded as part of the fluoroquinolone profile.

24 There is a huge amount of stuff in that  
25 paragraph. First off, in July of '01, Kahn is

1 acknowledging that both ofloxacin and levofloxacin have a  
2 greater tendon problem than the other fluoroquinolones.  
3 They have denied that issue today. They will not say that  
4 there is a problem, but back in July of '01, they were  
5 admitting that problem.

6 As one of the documents that may still be subject  
7 to a confidentiality order says, and I will tell you about  
8 it without pulling it up, they specifically say they don't  
9 want to put that in the label, the greater potential. It  
10 would be a killer.

11 Next thing it says, there is comparative animal  
12 data that suggests that the two agents were prone to induce  
13 lesions than were many other members of the class. There  
14 is a huge argument the defense makes about you don't use  
15 animal studies to talk about whether it's predictive or not  
16 predictive. Jim Kahn says the animal studies will tell you  
17 it's predictive. It's a problem.

18 How can they with a straight face come here and  
19 say animal studies are not relevant? Their own doc says  
20 it's relevant. The next sentence says, Reporting rates for  
21 ofloxacin associated tendinopathies have traditionally been  
22 higher than other fluoroquinolone agents. Defense has been  
23 saying all along that Floxin is irrelevant, ofloxacin.

24 Kahn thinks it's perfectly relevant. He's  
25 worried that the higher reporting rates for Floxin tell you

1 something about Levaquin. He thinks it's relevant. The  
2 defense doesn't. In our U. S. post marketing Levaquin  
3 experience, we see has a higher reporting rate for tendon  
4 disorders.

5 What is it that they say there? They've looked  
6 at their owned SCEPTRE database. The SCEPTRE database is  
7 their database of adverse events that they maintain. Our  
8 expert Cheryl Blume has gone to a great length to evaluate  
9 the SCEPTRE database year by year, period by period to show  
10 where in the rankings tendon disorders fit.

11 THE COURT: What is the timing of the Kahn memo?

12 MR. GOLDSER: July 26th, 2001, the day after he  
13 comes back from the meetings with Aventis and Daichi.

14 THE COURT: Wasn't there a follow-up label  
15 change, though, right after this?

16 MR. GOLDSER: There was. There was a label  
17 change that occurred in October 2001. It was done by the  
18 CBE. The changes being effected procedure, so defense by  
19 that action acknowledges that CBEs are available. What  
20 they said in that label change was that there is a problem  
21 with the elderly in corticosteroids. Two problems there.

22 Number one, it ignores the question of Levaquin  
23 worse than the other fluoroquinolone, like this paragraph  
24 is talking about. It doesn't talk about the comparative  
25 tendon toxicity whatsoever. The other problem is the

1 adequacy of that warning, and I can talk about that  
2 somewhere along the line, but basically they put it in the  
3 PDR.

4           You have seen the PDR. It's an eight and a half  
5 by eleven book. The 2005 version has 3,558 pages in it.  
6 The Levaquin warning, the Levaquin part appears on page  
7 2,445. The warning itself appears on page 2,448 in the  
8 lower left corner of three columns, and the only thing that  
9 defendant did in changing the label was to change one  
10 sentence in the middle of that paragraph on the lower left  
11 corner on page 2,448 of a 3,558 page document and say the  
12 doctor should have picked up that one sentence.

13           They never detailed it. They never did a dear  
14 doctor letter. They never did a seminar about it. They  
15 never did any published articles about it. They never did  
16 any of those things. So, yes, Judge, there was a label  
17 change after this.

18           But this point has to do with the analysis of the  
19 SCEPTRE database, which apparently the defendant did, never  
20 disclosed to us in discovery, which our expert Cheryl Blume  
21 did, reproduced, and found that tendon disorders were  
22 ranked as the number one disorder and were back to 1999 and  
23 consistently thereafter.

24           What else did Jim Kahn write on July 26th, 2001?  
25 He says, The agencies have several options, and he goes

1 through a list of possibilities. One of them is a concern  
2 about restricting Tavanic, which was the European name for  
3 Levaquin, to in-hospital use. That gets you to the same  
4 contraindication problem that sparfloxacin got to.  
5 Labeling changes would follow, and least onerous would be  
6 letting the company continue its current campaign of  
7 alerting doctors to the situation, which of course they  
8 were not doing.

9 This is the doctor talking about how to minimize  
10 the warning label so that they don't have economic, adverse  
11 economic impact. Farther down on that document they start  
12 talking about the epidemiology study that Europe wanted,  
13 and I've highlighted the section that reads, Moreover, the  
14 study envisioned struck many as very insufficient in its  
15 present design.

16 That's Aventis's proposed study. It might  
17 actually generate more damaging material unless careful  
18 thought were given to other fluoroquinolone and  
19 nonfluoroquinolone experience in the same database.  
20 They're worried about an adverse result if they do the  
21 proper study. They had to manipulate the study.

22 Ultimately, they did manipulate the study in our  
23 view. That was the Ingenix study, and we will talk about  
24 what they did with that. Mr. Saul will go into more detail  
25 than I will. You can see the precursor of manipulation of

1 the Ingenix study right after the Kitano meeting. The  
2 proper remedy is not to fault the agent but to seek remedy  
3 in either changing medical practice or more thoroughly  
4 advising physicians of the identified risk factors.

5 It's not Levaquin's fault. It's the doctors'  
6 fault. We have got to make sure the doctors don't use this  
7 wrong. There is nothing wrong with Levaquin. Of course,  
8 blame others. Isn't that always the case, blame the victim  
9 in situations like this?

10 The sine qua non of our efforts should be making  
11 the case that the European picture is distorted by medical  
12 practices and in no way implicates levofloxacin as the lone  
13 culprit. It's the doctors' fault. We need to consider  
14 doing the correct epidemiological study ourselves. We have  
15 far more at stake than does Aventis, and there would be no  
16 ambivalence clouding our commitment to doing it right.

17 Far more at stake? Ortho-McNeil had one  
18 antibiotic. Aventis had a bunch. If Aventis lost Tavanic,  
19 Levaquin, their revenues would not suffer. If Johnson &  
20 Johnson, Ortho-McNeil, lost Levaquin, they would be losing  
21 their number one drug. They had far more at stake, and  
22 that's all for that document.

23 Their mindset, the entire franchise was riding on  
24 a single toss. That's what Jim Kahn said again in his  
25 deposition. The stakes have gone up, Larry Johnson wrote

1 this, when the Germans suggested there was a problem with  
2 Levaquin. There was some discussion about contraindication  
3 occurring with the British advisor, Dr. Steven Evans, and  
4 the writing was that a contraindication would be tantamount  
5 to a withdrawal. They were worried about that.

6 The MCA, that's the British authority, they were  
7 proposing a label change, and this could lead to a bad  
8 result, which we have already detailed. Now this document  
9 is the one that I was talking about that I don't believe  
10 was used in the deposition, but it also had the provision  
11 in it that said we cannot accept a label change that would  
12 show Levaquin having a greater potential for tendon  
13 toxicity than any other fluoroquinolone. The study could  
14 be a nightmare. That would be the Ingenix study, if it  
15 came out wrong.

16 And finally one of the marketing people talking  
17 to the scientists about how to manage the study said,  
18 you've got to do whatever it takes. This is the marketing  
19 people talking now about how to do science, just as the  
20 science people were talking about how to do marketing with  
21 ultimately one goal, profits over people.

22 We have four categories of claims of bad acts  
23 that we believe are germane to this motion. First, the  
24 defendant deliberately disregarded patient rights  
25 concerning the warnings. Second, they manipulated the

1 scientific literature for their own economic purposes.

2 That's the Ingenix study.

3 Third, they deliberately disregarded existing  
4 scientific literature. There were, we count, 16 articles  
5 published by 2003 wherein either Floxin or Levaquin was  
6 shown to have a greater tendinopathic potential than other  
7 fluoroquinolones in the class. It was out there. It was  
8 not in JAMA. It was not in the Archives of Internal  
9 Medicine.

10 Dr. Beecher, our family practice physician in the  
11 Schedin case working in Edina, would not be seeing these.  
12 Some of them were internal documents, like the Aventis  
13 study that was given to the MCA. There were 16 articles  
14 that Johnson & Johnson had and should have known about that  
15 they disregarded.

16 Then on top of that what do they do is, they turn  
17 their sales force loose, and their sales force has one  
18 mantra: Tell everybody how safe Levaquin is, touting the  
19 high safety profile of this drug. They deliberately  
20 disregarded patient rights. They created a plan to  
21 maximize profits while avoiding safety issues.

22 Sitting around in board room 301 in the Kitano  
23 meeting, you didn't see anything in that James Kahn memo  
24 that said anything about safety issues and how do we fix  
25 the safety problems. It was how do we avoid the safety

1 problems in order to make sure we don't lose any money.

2 They purposely sought to avoid label changes.

3 I had an e-mail from Dr. Noel, one of the medical  
4 people involved in this. That's attached to this, but I  
5 highlight back for you the notion that I mentioned before  
6 about how they refuse to incorporate anything in their  
7 label change about Levaquin being worse than the other  
8 fluoroquinolones.

9 They knowingly decided not to share the warnings  
10 information with the public. One of the documents that I  
11 have that the defendant has finally acknowledged is a set  
12 of handwritten notes from yet another doctor, Chuen Yee,  
13 from Johnson & Johnson, sitting at the Kitano meeting, and  
14 that documents says in her handwriting, Not share with  
15 public, and it's talking about the French agency reports.  
16 Don't tell anybody about it.

17 They ignored their own published literature and  
18 how best to communicate warnings to doctors. I mentioned  
19 Dr. Fife. He's one of the doctors involved with Johnson &  
20 Johnson. He's an epidemiologist. One of the epidemiology  
21 studies he published, and I'm not sure but what this  
22 article is marked confidential. Let me just take a quick  
23 look here.

24 No, they didn't mark this one confidential. What  
25 Dr. Fife says at the end of his article, if I have it

1 highlighted -- let's see if I can pull that up for you. He  
2 did an epidemiology study to determine what is the most  
3 effective way to communicate warnings to doctors, and what  
4 he finds in the last sentence is the most telling I think.  
5 The key characteristics of a successful drug warning appear  
6 to be specificity, prominence, brevity, no reliance on  
7 secondary information, publicity and in-person discussions.

8           You've got to do stuff other than bury it on the  
9 lower left corner of page 2,448 of the PDR when that book  
10 comes out every year and don't tell a doctor about it.  
11 Their own doctor says, their own epidemiology department  
12 tells how you should be doing that. They ignore their own  
13 published literature and how best to communicate with  
14 doctors.

15           They intentionally buried the warning, as I have  
16 described to you. They failed to send a dear doctor  
17 letter. There were dear doctors letters sent, if I get the  
18 countries right, in France, Italy, Belgium, Germany,  
19 Austria, and I'm missing one. There were six of them, all  
20 in 2001 and early 2002, about the corticosteroid elderly  
21 problem. Was there one sent in the United States? No.

22           Dr. Canabarro from Aventis was deposed, and what  
23 she said in her deposition was, she was asked, you know,  
24 why do you send out a dear doctor letter, and her response  
25 was, well, you know, we had it in the warnings. But why

1 did you send out the dear doctor letter? Because the  
2 warning wasn't enough, and we wanted to make sure to  
3 communicate with doctors. Aventis did it. Johnson &  
4 Johnson didn't.

5 They deliberately did not train their sales  
6 representatives to proactively call out label changes to  
7 doctors. I deposed Teresa Turano two weeks ago. She was  
8 the 30(b)(6) corporate representative on sales training.  
9 She didn't know much, but what was clear from her was that  
10 there was no policy to tell sales representatives that  
11 whenever there is a label change you have got to tell  
12 doctors.

13 What they did do is, they handed out a copy of  
14 the package insert every time they went there,  
15 theoretically, but that doesn't mean they said to the  
16 doctor, you know, take a look here. There is a label  
17 change. I want to make sure you're aware of this. They  
18 did not do that.

19 They did do that with the black box. The sales  
20 force was told proactively, tell doctors about the black  
21 box. Were they told proactively to tell doctors about the  
22 black box? Were they told proactively to tell doctors  
23 about that 2001 label change? According to the corporate  
24 representative, there was no such policy.

25 They deliberately didn't issue press releases

1 publicizing changes. I deposed Greg Panico last week, the  
2 corporate representative on press releases. He, too,  
3 didn't know a lot, but what he did say was there was no  
4 policy to initiate press releases about label changes. We  
5 went through a litany of documents. They kept track of  
6 every news article.

7           There were clear press releases issued about new  
8 indications that the FDA had approved, but was there any  
9 indication whatsoever that they issued a pretty release on  
10 any label changes? Not a one. They didn't undertake any  
11 seminars, public speaking engagements, lunch or learn  
12 trainings.

13           They didn't educate doctors in the manner that  
14 they otherwise do educate doctors about new indications.  
15 They didn't publish articles talking about the risk of  
16 tendon disorders, and I will come back to that in a little  
17 bit when I talk about the publication plan and the ghost  
18 writing.

19           They manipulated the Ingenix study for their own  
20 economic purposes. The Ingenix study started to appear in  
21 discussions in the late fall of 2001. Aventis made a  
22 proposal about the protocol. The idea was that they would  
23 respond to the French authorities. The French authorities  
24 wanted to know what was the comparative tendon toxicity  
25 between Levaquin and the other fluoroquinolones.

1           The Johnson & Johnson response was -- and Aventis  
2           was going to do a study that said that. Johnson & Johnson  
3           said we can't afford that study. If we end up with a bad  
4           result, we're in trouble. So they started taking control  
5           of the study from Aventis, and they slowly but surely  
6           turned the battleship around to change the focus of the  
7           study from a comparison between fluoroquinolones to talking  
8           about fluoroquinolones in general and the impact on the  
9           elderly and corticosteroids, because by that time they had  
10          already decided to include that warning in the label.

11                 And so if they found that there was a negative  
12          impact, no big deal. It was already in the label. They  
13          already had a strategy for that. So they were going to  
14          figure out a way to manage the Ingenix study so that they  
15          would get the result that they wanted. So they manipulated  
16          the one study to achieve an outcome that was in their best  
17          economic interests.

18                 They took it over from Aventis. They controlled  
19          the study with Ingenix. I will talk about that for a  
20          second. The protocol that was written, it was drafted by  
21          Dan Fife. It was discussed between Dan Fife and John  
22          Seeger at Ingenix.

23                 There were meetings to talk about the protocol.  
24          There were exchanges of drafts on how to do the protocol,  
25          the type of study that it was was developed by Johnson &

1 Johnson in discussion with Ingenix. I mean, they did the  
2 whole protocol process.

3 To be sure, I mean, John Seeger was involved in  
4 this, but Johnson & Johnson really controlled the protocol  
5 process. Once the protocol was set, it was just a matter  
6 of filling in the numbers by mostly administrative  
7 mechanism, although we certainly have complaints about how  
8 John Seeger did that, and I will talk about that.

9 They avoided comparing Levaquin with other  
10 fluoroquinolones as was requested in Europe. All the items  
11 on the bottom are references to documents, and if the  
12 hyperlink works, you could pull up the documents. They  
13 changed the desired outcome. Europe wanted to know what  
14 was the problem related to tendonitis and tendinopathy.

15 Johnson & Johnson said we can't do that. It has  
16 got to be tendon rupture. Ostensibly the reason is because  
17 tendon rupture is better defined. It's easier to identify  
18 what constitutes a tendon rupture, but really what they're  
19 saying at that point in time is that doctors don't know how  
20 to diagnose a tendinopathy and they won't trust  
21 tendinopathy diagnoses.

22 Paul Van der Linden in the Netherlands whose four  
23 studies, including his PhD thesis, talked about how Floxin  
24 was worse than the rest, focused on tendinopathy and tendon  
25 rupture. He was able to distinguish between tendinopathy

1 and its relative risk compared to other drugs and to  
2 placebo and also tendon rupture compared to other drugs and  
3 placebo.

4 He could do it. It was academically acceptable  
5 to people accepting his PhD thesis, but that was not good  
6 enough for Johnson & Johnson. The reason? Because there  
7 were fewer tendon ruptures than tendinopathies, and as a  
8 result the relative risk was going to show lower, they  
9 would get a better number.

10 They manipulated the power estimates of the  
11 study. I don't know to what extent you're conversant with  
12 the notion of power, but power tells you the ability to  
13 make accurate predictions about epidemiology studies. If  
14 you start out with power that is wrong, it's too high. If  
15 the power is at four when you're going to find a relative  
16 risk of two, what you are going to end up with as a result  
17 of that is a confidence interval that is very wide.

18 In order for you to have statistically  
19 significant results, the narrower the confidence interval  
20 the better, and most importantly, if the lower bound of the  
21 confidence interval is over one, you know that at worst  
22 it's still more statistically significant than random. One  
23 is random.

24 So when you have got a wide confidence interval  
25 that results in a lower bound being below one, you can say

1 with honesty this is statistically not significant, but it  
2 all stems from where you started. If you start with the  
3 wrong power estimate, you end up with a wide confidence  
4 interval and no statistical significance.

5 If you take the trouble to go through the litany  
6 of testimony from John Seeger that is listed on that page,  
7 you will see he admits that that's true and that they knew  
8 it going in, that they picked the wrong power. It was a  
9 manipulated study.

10 They minimized the number of elderly contained in  
11 the study data. I know Mr. Saul will talk about that.  
12 They improperly included children in the study. Mr. Saul  
13 will talk about that. John Seeger admits that that's true.  
14 They incorrectly identified what constitutes a tendon  
15 rupture for the study by having a nonmedical doctor,  
16 Seeger, do the study.

17 In particular what you might pay attention to on  
18 that slide is the bullet point saying testimony of Seeger  
19 regarding Schedin. We happened to pull out Mr. Schedin's  
20 medical record where it talks about whether he has got a  
21 tendon rupture or not a tendon rupture. It says tendon  
22 tear.

23 We asked Dr. Seeger, Is this a tendon rupture  
24 that would be included as a positive finding in your study.  
25 He said, no, this would not be a tendon rupture in our

1 study. Our plaintiff here, who has clearly defined tendon  
2 ruptures and his doctors have all said so, his treating  
3 doctors have said so, was not a tendon rupture for purposes  
4 of John Seeger's study. That's how badly defined some of  
5 these tendon ruptures were.

6 Why? Keep them out of the study and keep the  
7 numbers low. There was a medical record review for  
8 evaluating tendon ruptures, but there was no such medical  
9 record review for tendonitis cases which was used as a  
10 covariate. It was an internally inconsistent study.

11 Seeger is not blinded during the study. He knew  
12 which cases had fluoroquinolone use and which were not.  
13 Dan Fife, Johnson & Johnson's own witness, says that as a  
14 result the study is invalid. They destroyed abstracts. We  
15 wanted to reproduce the study. In order to reproduce the  
16 study we needed the abstracts and the medical records that  
17 they used to determine what was a tendon rupture and what  
18 was not. They have been described.

19 They admit it. Seeger admits that in the fall of  
20 2006, three months after the article was published, they  
21 destroyed these documents. That's contrary to the  
22 guidelines published by the International Society of  
23 Professional Epidemiologists, ISPE, which requires that  
24 such documents be held for five years.

25 Normally you wouldn't think that would be such a

1 big deal except the guidelines were written in part by  
2 Seeger's boss at Ingenix, Alec Walker. Walker said, I  
3 don't know the guidelines. Are there guidelines? These  
4 guidelines go back to 1996. Walker wrote them in 1996.  
5 They were revised in 2000, 2004 and 2007, if my memory  
6 serves me correctly.

7 Walker doesn't know them. Seeger doesn't know  
8 them. They destroyed the documents in contravention of  
9 guidelines that they wrote. Mind boggling. They ignored  
10 the existing scientific literature. I told you about the  
11 16 articles. They lied to the FDA about comparative tendon  
12 toxicity of fluoroquinolones.

13 Finally, on the converse side, their marketing  
14 efforts. They touted Levaquin's excellent safety profile  
15 without disclosing its risk and trained its sales  
16 representatives in this manner. I have got a pile of  
17 documents that show that. The do and don't document that  
18 is on there do tout the excellent safety profile of  
19 Levaquin.

20 The quick tips guide that is on the bottom there,  
21 I worked with Teresa Turano and went through much of that  
22 verbatim. I said, does this paragraph have anything about  
23 safety in it? No. Does this have anything about tendon  
24 ruptures in it? No. Does this have anything about  
25 warnings on tendon ruptures? No. Does this have anything

1 about comparative tendon toxicity? No.

2 All over the place there is nothing about tendon  
3 warnings, and it's all about the excellent safety profile  
4 of Levaquin. They knowingly marketed to the elderly  
5 population. Again, the quick tips guide will tell you  
6 that. They marketed it as first line therapy. Levaquin is  
7 a good drug for certain circumstances. We don't dispute  
8 that.

9 For people who are seriously ill, it will do what  
10 it's supposed to, but if you're got a sinusitis or an acute  
11 bacterial exacerbation of chronic bronchitis, like John  
12 Schedin did, you don't use Levaquin. He had one trial on  
13 Zithromax. Could easily have gone back to another trial on  
14 Zithromax or another less potent antibiotic, but this was  
15 marketed like candy, samples left, right and sideways.  
16 They had millions of dollars in samples for first line  
17 therapy for these indications that were hardly severe  
18 enough to warrant them.

19 They did ghost writing. From 1994 to 2002,  
20 DesignWrite, their hired gun, caused to be authored two --  
21 144 papers on either Floxin or Levaquin, touting its  
22 benefits. Of those 144 papers, 13 of them had the word  
23 "safety" in the title, and only one of them had anything to  
24 do with tendons, and that was a published, published paper  
25 on children and tendon disorders. Nothing about the

1 elderly. Nothing about corticosteroids. Nothing about any  
2 of the issues where Levaquin is worse than any other  
3 fluoroquinolone, and that's only through 2002.

4 In 2002 they spent a million dollars with  
5 DesignWrite on ghost writing alone. There was a lot more  
6 money spent with DesignWrite in that year. They used the  
7 Speakers Bureau as a promotional tool. Defendants' own  
8 expert John Segreti who is going to talk about  
9 Mr. Schedin's particular circumstances and case specific  
10 and also what you use Levaquin for.

11 I asked him -- he is on the Speakers Bureau, so  
12 they are bringing in a Speakers Bureau person as their  
13 expert witness, which is kind of curious. I asked him what  
14 he did when he was on the Speakers Bureau. He gave talks.  
15 I said, well, were they promotional. He said, of course  
16 they were promotional.

17 Well, why were they promotional? Because I was  
18 touting the use of Levaquin. It wasn't educational about  
19 disease. It was about how best to use Levaquin. They were  
20 promotional.

21 So at the end of the day, Judge, we have lots of  
22 good reasons why we believe defendant deliberately  
23 disregarded the rights of the plaintiffs, including John  
24 Schedin, intentionally, consciously, knowingly, willfully  
25 and with marked indifference. That's our evidence.

1           You don't have to, you shouldn't listen to any  
2           contrary evidence or challenges or cross-examination by  
3           defendant because that's not what the law allows or  
4           requires. We think the motion should be granted. Thank  
5           you very much.

6           THE COURT. Thank you, Mr. Goldser.

7           Mr. Saul, did you have something?

8           MR. SAUL: Good morning, Your Honor.

9           THE COURT: Good morning.

10          MR. SAUL: Louis Saul on behalf of plaintiffs.

11          Mr. Goldser talked at some length about the  
12          Ingenix study, and I will fill in the gaps. I realize our  
13          time is limited here. Just to go back, Johnson & Johnson  
14          had nothing to do with the European situation. Aventis,  
15          their trading partner in Europe, was asked to do studies  
16          because of the signal in Europe that there were tendon  
17          problems, particularly among the elderly, emphasis added,  
18          and particularly with corticosteroids.

19          What the defendant was hoping to avoid and worked  
20          to avoid -- may I approach -- was to have this, this  
21          warning in the label. This is the warning that eventually  
22          got into the label. This is the black box warning that got  
23          into the label in November '08. Fluoroquinolones,  
24          including Levaquin, are associated with an increased risk  
25          of tendonitis and tendon rupture. The risk is increased on

1 those over 60 and those on concomitant therapies  
2 respiratory, heart and lung recipients.

3 They kept this warning from being placed in the  
4 PDR, in the package insert, for seven years. During that  
5 seven years, their sales were about 13 billion dollars. By  
6 keeping this warning out for seven years, this company  
7 earned themselves 13 million dollars, and we believe that  
8 that evidence in itself is enough to get us to the punitive  
9 damages claim.

10 However, how did they do it.

11 THE COURT: Is this the warning that is on right  
12 now?

13 MR. SAUL: This is the present day warning.

14 THE COURT: Go ahead. I will ask you a question  
15 about that later.

16 MR. SAUL: Sure. So what did they do? They had  
17 no interest in Europe. In fact, they told the Court during  
18 our motion practice that they had no relationship with the  
19 European authorities and they didn't want to give us  
20 documents related to that, that they actually went and took  
21 over this study. They took it away from Aventis because  
22 they said if we don't do this study and we don't get the  
23 proper results, essentially we're dead. Levaquin is off  
24 the market.

25 So what did they do? They hired this company

1 called Ingenix who had done numerous other studies for  
2 them. There was a young doctor there by the name of John  
3 Seeger who had just become an employee, and they had him  
4 conduct the studies. Mr. Goldser said they designed the  
5 protocol. What did they do in the study?

6 If I may give you another document, Your Honor.  
7 This was prepared by me, and this is how they intentionally  
8 manipulated the study. The first they wanted to do, the  
9 European authorities wanted to study -- the issue was among  
10 the elderly and corticosteroid use. What did Johnson &  
11 Johnson do? They intentionally left out elderly from the  
12 study.

13 This document that I just handed you was from the  
14 original protocol of this Ingenix study. If you will see  
15 here, table 1 talks about the UnitedHealthcare research  
16 database population. If you'll go down to the bottom, 60  
17 to 64 and 65 plus, you will see that in their database,  
18 there was only 4.7 percent of, let's for lack of a better  
19 term, the aging population. I'm in there. Just leave it  
20 like that.

21 You will see in table number 2 in the census  
22 bureau, there were 16.2 percent of the population being  
23 over 60. So they chose a data -- Aetna was going to use a  
24 different database, but they took this away and used this  
25 particular database that underrepresented the elderly.

1       What else did they do?  Levaquin was contraindicated for  
2       children, for pediatric use.  Contraindicated, you can't  
3       use it for pediatric use.

4                You will see in the general population, there is  
5       29 percent, and in their database there is 29 percent in  
6       approximate numbers.  They included this 29 percent, the  
7       children, in the study.  So what they did is, they kept the  
8       elderly out.  They included children.  Children can't even  
9       take Levaquin.  The elderly, the focus was on the elderly.  
10      They cut that down.  Okay.

11              So what did they do?  So they intentionally  
12      excluded the elderly and included children.  But then what  
13      happened?  They did their study.  Part of their study was  
14      to get this study published in certain journals.  Those  
15      journals are the journals that most of us have heard about.

16              For instance, in New England -- I won't go  
17      through them all.  Five journals, the New England Journal  
18      of Medicine and the first line journals.  They could not  
19      get this study published anywhere.  What did they do?  They  
20      went to -- Johnson & Johnson and Ingenix, they were members  
21      of a society, and Ingenix was the head of the society.  
22      They got it published in that society's journal.

23              No one else would take it.  The study was  
24      concluded in 2003.  2006 it got published.  Lo and behold  
25      three or four months after it got published, they destroyed

1 the data. They went and they did medical review of a  
2 certain number of the patients in this study, and you have  
3 to keep this data because once you publish something, other  
4 researchers have to be able to duplicate the study.

5 What happened to the data? Dr. Seeger testified,  
6 we don't -- we didn't really know what happened. I'm not  
7 sure what happened, and he went on and on. Finally, we got  
8 him to admit, and I just want to read to you -- at any  
9 rate, Dr. Seeger admits, admits that under his tutelage or  
10 under his direction that he caused all the documentation to  
11 be destroyed regarding the study. This is, forms the basis  
12 also of our motion, our *Daubert* motion.

13 No one can duplicate this study. They also  
14 created an algorithm to define who was in the case. They  
15 can't find that algorithm. All the documentation is gone.  
16 That in itself, the intentional destruction of the data,  
17 they kept their product on the market for nine years or  
18 eight years, is enough to allow us to amend the, the  
19 complaint, and I believe it's enough for the jury to enter  
20 a substantial award.

21 I feel that our time is limited, but each of  
22 these dotted areas is covered in our brief extensively, and  
23 I would like to incorporate our motion in limine regarding  
24 Dr. Seeger into this because rather than me go on and on  
25 about the study, I think it's all well depicted in our

1 brief.

2 THE COURT: Thank you, Mr. Saul.

3 MR. SAUL: Thank you, Your Honor. Did you have  
4 any questions about the black box?

5 THE COURT: No. That's fine. I may address it  
6 later in the hearing.

7 Mr. Dames?

8 MR. DAMES: Thank you, Your Honor. Your Honor, I  
9 just want to start from, actually maybe just the simplest  
10 of all is to start from the beginning, and that is when the  
11 drug was first marketed in 1997. There has much been made  
12 so far in the arguments concerning concealment, omissions,  
13 lack of warning, refusal to include things in the warning  
14 that I would like to refocus this as to what took place in  
15 the very beginning when the drug was first marketed.

16 From its inception, and the Court is well aware  
17 because we've said it many times, when it was first  
18 marketed, there has been a tendon rupture warning in the  
19 label. Not hidden, not in any way buried in a mass of  
20 language, prominently mentioned in the warnings.

21 At the time that Mr. Schedin received his  
22 prescription for Levaquin, the warnings had been updated as  
23 early as 2002 -- well, let me first go back to October of  
24 2001. The warning was altered to include a reference to a  
25 heightened risk in the elderly, potential risk with the

1 elderly taking corticosteroids.

2 That was in response to the events and the data  
3 that had been received in Europe about the experience and  
4 adverse reaction reports from the use of Tavanic, the --  
5 Levaquin is marketed in Europe, and the company through a  
6 change is being effected, that is on its own initiative,  
7 incorporated the information that was coming from Europe to  
8 include that in the warning on its own.

9 The FDA approved it at the company's instigation.  
10 They approved that warning. It was that warning with a  
11 very slight amendment in 2004. That was the warning the  
12 prescribing physician for Mr. Schedin received.

13 Now, in Europe the reports, the adverse reaction  
14 reports that were received in Europe, showed variances  
15 within the different European countries. Germany had a  
16 much lower rate of reporting than did France. When those  
17 things were investigated, when the scientists and  
18 researchers looked at what were the reasons for divergence  
19 between the European countries, they determined that in  
20 France, Levaquin was prescribed and Tavanic was prescribed  
21 predominantly for upper respiratory tract infections, and  
22 there the French physicians used corticosteroids a  
23 significant percentage of the time when they used Levaquin.

24 Now, the debate has been, you know, what  
25 significance is that. When the meeting occurred at the

1 Kitano Hotel, not quite as luxurious. I have actually  
2 stayed there. When the meeting was held at the Kitano  
3 Hotel to evaluate the situation and determine what should  
4 be done to investigate it, now remember already in place  
5 was J & J's CBE label change -- the label change occurred  
6 in October. I'm sorry. Already --

7 J & J incorporated that information in October  
8 that it learned, but in addition it wanted to do an  
9 investigation and a study, as did Aventis. Aventis does  
10 their own studies, a quick and dirty analysis, it was put,  
11 to look at the situation to respond to the French and  
12 European regulatory authorities. J & J decided it wanted  
13 to use the largest database then available, the  
14 UnitedHealthcare database.

15 Contrary to what you have heard so far, Your  
16 Honor, the Aetna database, an alternative, was not even  
17 available to be used. They couldn't use it. Why did they  
18 use UnitedHealthcare database? Well, it afforded J & J an  
19 opportunity to have access to medical records. Not all  
20 databases that were used would give you the access to the  
21 medical records.

22 And as I said, it was an exceptionally large  
23 database and would provide one of the best experiences to  
24 evaluate to see what was the frequency, what was the  
25 incidence of tendon rupture on Levaquin and what was the

1 incidence of tendon rupture on some other factors, for  
2 example, other fluoroquinolones and to evaluate --

3 I mean the study itself clearly was published by  
4 Dr. Seeger, included other factors besides Levaquin. It  
5 also evaluated corticosteroid use and some other  
6 predisposing factors. Now, why was tendon rupture used as  
7 a measure? Was it done to manipulate the data, to somehow  
8 hide something? No.

9 It was determined that the most objectively  
10 verifiable diagnosis that could be used in the study was a  
11 rupture. Not tendinopathy. Tendinopathy can be a wide  
12 variety of things. It is like 70 diagnostic codes are  
13 related to tendinopathies. So it could be confused with  
14 muscle tears. It could be confused with other kinds of  
15 diagnostic end products. So it was made, it was determined  
16 to use tendon rupture as the objectively verifiable point.

17 The diagnosis of tendon rupture by a physician  
18 was operative. Now what is wrong with that? Very, very  
19 little. Dr. Van der Linden used tendon rupture as the  
20 outcome in his own study.

21 Now, I want to remind the Court that J & J was  
22 very responsible in addressing the issue head on. It  
23 wanted to do the study on its own, not because it wanted to  
24 manipulate the results. Dr. Kahn testified quite clearly  
25 that what they wanted to do was the correct study. They

1 wanted to do it correctly. They wanted to make certain it  
2 was done right, and that's why they did the study the way  
3 they did, and that's why they did it rather than rely on  
4 any other company to do it on their behalf.

5           What was the outcome of their investigation?  
6 What was the outcome of their research? The French and  
7 European -- well, the European regulatory authorities  
8 evaluated not only the Johnson & Johnson sponsored study  
9 that was performed, and let's make this distinction clear.  
10 It was performed by Ingenix. J & J participated in the  
11 protocol. It helped plan the protocol of this study.

12           It did not conduct the study. That was done  
13 independently by Ingenix, and Dr. Seeger made the decisions  
14 concerning the development of the study together with other  
15 employees at Ingenix and the development of the algorithm  
16 which defined and decided which were cases and which were  
17 not.

18           Much reference has been made to destruction of  
19 medical records. Dr. Seeger in the course of an office  
20 move after the study was published, as plaintiffs state,  
21 lost the medical records involved in the study. It had  
22 nothing to do with Johnson & Johnson. Johnson & Johnson  
23 certainly had no relationship to any loss of the medical  
24 records, but it was inadvertent, and it was done during the  
25 course of his office move, as he testified.

1           There was a reference made to whether his study  
2           was blinded. Dr. Seeger pointed out, his study, he was  
3           blinded as to which fluoroquinolones were used by the  
4           people involved in the study. We could go on and on with  
5           how the study was designed. Were the elderly intentionally  
6           excluded? That's absolutely false. Here is a classic  
7           example of how the characterization by plaintiffs is so  
8           unfair.

9           The UnitedHealthcare database, of course, the  
10          basis of that database are the people covered under the  
11          UnitedHealthcare. That, there would be, because of  
12          Medicaid -- because of Medicare, there would be a possible  
13          underrepresentation of the elderly. That was recognized,  
14          and that's why the elderly and a Medicare database were  
15          added to the study.

16          So there wasn't any intentional exclusion. They  
17          were in fact included. Then it was contrasted with whether  
18          there was an intentional inclusion of children to also skew  
19          the results of the study. Children were not intentionally  
20          included. The database includes children. There were no  
21          Levaquin cases of tendon rupture involving children. There  
22          were no skewed results because of children, but you take a  
23          database as it comes, and it includes the span of ages in  
24          the database, so of course, the age range of children who  
25          would have been included.

1           The tears were excluded, according to Mr. Saul,  
2           in the study. If Levaquin, if there was a tendon rupture  
3           defined as having occurred with Levaquin by the prescribing  
4           doctor, it could be defined as a complete tear, it would be  
5           included. So we are really ending up talking about and  
6           debating the merits of a scientific protocol openly arrived  
7           at, submitted to the FDA, shown to the European regulatory  
8           authorities who in turn evaluated the published literature,  
9           Aventis's own studies and the Seeger study.

10           And they recognized the limitations of each,  
11           including the Seeger study, and what do they come out with  
12           after the purported suggestion -- it isn't purported. It  
13           was a suggestion by one of the assessors earlier on that  
14           the label be altered to include a statement concerning a  
15           greater use in the risk of Levaquin over the other  
16           fluoroquinolones.

17           That was rejected after all of the evidence was  
18           in by the European regulatory authorities, and the reason  
19           it was rejected was clearly stated that the data was  
20           insufficient to make any differentiation between  
21           fluoroquinolones and tendon rupture, and it is worthwhile  
22           to remind ourselves of exactly what the European health  
23           authorities after all of the data was in, up-to-date for  
24           them, in 2003.

25           And it says, and this is one of

1 Plaintiff's Exhibits, Exhibit 87. Under paragraph 8, and  
2 we mentioned it as well in our brief, Your Honor, the  
3 conclusions, it states, The morbidity and frequency of the  
4 suspected adverse reaction, that is, very rare and not  
5 fatal outcome which generally recovers, must be weighed  
6 against the nature of the benefits and indications for  
7 treatment with levofloxacin, reduction in morbidity and  
8 mortality of respiratory tract infections and other  
9 infections when considering the need for further studies  
10 and regulatory action.

11 They conclude, No further action -- this is on  
12 the next page -- given the rarity and nonlethality of  
13 adverse reactions, this is justified on the following  
14 grounds. Absolute risks of fluoroquinolone associated  
15 tendon rupture are very rare, and furthermore, the  
16 population attributable risk is very low.

17 Although we cannot exclude a slightly higher risk  
18 of tendon rupture with levofloxacin or ofloxacin, currently  
19 available data are inconclusive. Such estimates are likely  
20 to be rare or very rare. SPCs, that is a labeling, for  
21 levofloxacin products have been updated with adequate  
22 warnings. Further analysis of existing data are unlikely  
23 to be helpful.

24 There were several things in that conclusion that  
25 are important. Even considering all of the studies, even

1 considering the state of the animal data, considering all  
2 of the issues that plaintiff have put forth today about the  
3 adequacy of the studies, disagreeing with some, agreeing  
4 with others, the European regulatory authorities decided  
5 that the heightened risk label change was not necessary.  
6 There was no evidentiary basis for it.

7           They also, however, said something very important  
8 in this conclusion, and that is the benefits of Levaquin in  
9 the treatment of upper respiratory infection. There are  
10 benefits to this drug, and that is in part part of the  
11 passion that arises from Dr. Kahn. The benefits of  
12 Levaquin have been proved repetitively, and they are agreed  
13 to by everyone in this litigation.

14           At the trial of this case, you will hear from  
15 every expert witness, plaintiffs' and defendants' alike,  
16 that Levaquin is efficacious and is very valuable. It is a  
17 good drug. Quite simply, they have testified already that  
18 it is a good drug.

19           We have pointed out in the brief that Dr. Zizic,  
20 one of the plaintiffs' principal experts in this case,  
21 prescribes Levaquin, uses it to this day. Uses it, in  
22 fact, under the condition -- well, let me backtrack.  
23 Dr. Zizic took it himself. It actually cured his  
24 infection, a very severe infection which he had.

25           So he obtained the benefit of Levaquin himself.

1 He gives it to his patients from time to time, and there is  
2 no testimony from either Dr. Zizic or any other expert  
3 witness in this case that the use of Levaquin under the  
4 conditions of use in Mr. Schedin was somehow inadequate or  
5 inappropriate.

6 So in the midst of all of this characterization  
7 of how there was a clear disregard of the safety of  
8 patients, we have a unanimity of opinion as to the  
9 necessity and utility of the drug. We have a unanimity of  
10 an opinion that it should be used in the kinds of  
11 infections, upper respiratory tract infections, for which  
12 Mr. Schedin received the drug.

13 We have also heard about, it is not to be used as  
14 a first line of defense therapy for certain indications.  
15 Well, taking Mr. Schedin's case, for example, there will be  
16 no testimony, there is certainly none based on the expert  
17 reports of the depositions, that Mr. Schedin was not an  
18 appropriate candidate at the time he got Levaquin for  
19 Levaquin.

20 There are no indications in any label or any  
21 suggested indications in the label or contraindications  
22 which would minimize the use of Levaquin or have it as a  
23 second line of use. The published guidelines to this day,  
24 the Sanford Medical Guide, the Infectious Disease Society  
25 published guidelines, call for Levaquin to be used as a

1 first line therapy initially in upper respiratory tract  
2 infections.

3 So the current state of medical knowledge by  
4 neutral and expert physicians, by responsible and  
5 referenced medical guides all call for the use of Levaquin.  
6 Levaquin is in fact the most efficacious, the best  
7 antibiotic for upper respiratory tract infections.

8 So if I can mirror, even slightly, the belief  
9 that someone like Dr. Kahn and others brought to how  
10 important the drug was to be used in the current  
11 respiratory season in his memo and to push for the right  
12 study, the correct study, the properly done study, the  
13 mischaracterization of the memo and of Dr. Kahn in this is  
14 truly horrendous.

15 Dr. Kahn's attempts, J & J's attempts was to do a  
16 study using the largest healthcare database then available,  
17 to use it for a measure of outcome which was the most  
18 clearly and objectively verifiable, and they hired Ingenix  
19 to perform and conduct that study. None of the data that  
20 has been developed to this day shows that Levaquin has any  
21 greater risk of tendon rupture than any other  
22 fluoroquinolone.

23 The data referenced by plaintiffs in their brief,  
24 the information that can be gleaned from it is, you either  
25 have data on ofloxacin. You have no reference to Levaquin

1 and tendon rupture in those studies. You have suggestions  
2 on animal data as to comparative toxicities, but virtually  
3 none that any authority considered relevant and probative  
4 of the differential toxicities.

5 So how can anyone conclude that what shouldn't be  
6 in the label, what is not in the label anywhere today, was  
7 somehow the result of manipulation by J & J earlier? How  
8 can anyone conclude that something not required by any  
9 regulatory authority to this day is the by-product of a  
10 manipulation by J & J and a clear disregard of public  
11 safety by J & J earlier?

12 Added to that is, these attempts through  
13 marketing efforts to cloud and conceal and hide and ghost  
14 writing and detail people to call on physicians and not  
15 mention safety. Every visit that a sales representative  
16 makes upon a physician includes the prescribing  
17 information.

18 They don't just get it from the PDR, although  
19 that's a highly reputable source. They get it every time a  
20 sales rep calls on them. They get it prominently mentioned  
21 in the label. It's not hard to find, and the physicians,  
22 now we have taken enough prescribing physicians I've  
23 reminded the Court to this day. The physicians know about  
24 tendon rupture.

25 If there is one thing that we find consistently

1 is that the prescribing physicians are aware of tendon  
2 rupture, including Dr. Beecher. He testified he knew of  
3 tendon rupture at the time he prescribed the drug to  
4 plaintiff. Plaintiffs asked, were you aware of the fact of  
5 corticosteroid and the risk of elderly, and in all  
6 fairness, Dr. Beecher said he didn't remember that he was  
7 aware of that at the time.

8 I asked him, Did you have this label, and I read  
9 him that label, and he said, yes, I did have that  
10 prescribing information at the time. More importantly, in  
11 this case, the actual prescribing physician turned to the  
12 plaintiff who was there and said to him, I'm very sorry.  
13 This is all my fault. Not the drug company misled me, not  
14 based upon what you have told me to this day and what  
15 plaintiffs' attorneys have told me do I feel like the  
16 company consciously disregarded your safety, not that I  
17 felt I was manipulated by anyone, not that I looked at any  
18 other information from any other source and was misled,  
19 none of that.

20 It was, this was my fault. Am I blaming the  
21 doctor? Frankly, no. The doctor did the proper thing.  
22 Mr. Schedin was cured of his infection. He suffered an  
23 adverse reaction, but that is not the sign or the sole  
24 reason to hold any drug company culpable when it has  
25 adequately warned and the company did. Hardly a case for

1 punitive damages. Hardly a case showing an intentional  
2 disregard for the safety.

3 Now, I just want to summarize and conclude, Your  
4 Honor, that plaintiffs claim that there was a plan to  
5 conceal and failed to disclose the heightened risk. There  
6 was no plan documented anywhere here. There is no level of  
7 agreement or anything that can diagram an effort to conceal  
8 and disregard the public safety. They document no such  
9 plan.

10 Plaintiffs also failed to demonstrate evidence of  
11 a heightened risk. As I have said repetitively, no expert  
12 or regulatory agency has concluded there is a greater risk  
13 to this day. The only ones to offer that opinion, the only  
14 ones that will come to the Court and discuss heightened  
15 risk are plaintiffs' retained experts who actually learned  
16 of the information and read the literature available on the  
17 drug for the first time, by and large, when they were  
18 retained.

19 They didn't have the level of experience and  
20 knowledge that could have afforded them the opportunity to  
21 have that opinion before it. Regulatory agencies have  
22 specifically reviewed the data as I have suggested that  
23 plaintiffs claim and cannot establish and deny that there  
24 is a greater risk and have never suggested that J & J  
25 should have put that in its label.

1           Plaintiffs argue that simply -- they argue that  
2           what that really shows, and I've heard this before, is  
3           actually how well the plan worked. The fact that no one  
4           has taken any action to show them that our unidentified  
5           plan has actually had its intended purpose, met its  
6           intended purpose.

7           Any efforts made by the company to investigate  
8           the issue, submit the results to the regulatory agency and  
9           publish the results are claimed by plaintiffs to be part of  
10          this illicit and unidentified plan. The very act that J &  
11          J wished and did a study, sponsored a study by Ingenix and  
12          wanted to do the correct study is taken as an effort to  
13          conceal the truth.

14          It is almost a bit Orwellian that an effort by  
15          the company to find out what it believed to be would be the  
16          most reliable and correct answer to date is taken as  
17          conduct to justify the imposition of punitive damages, for  
18          a product which remains on the market and is to this day  
19          considered to be a premier antibiotic with an ample warning  
20          about tendon rupture.

21          So it is difficult to conceive of a less  
22          appropriate situation and a less appropriate drug to find  
23          that the defendant acted in intentional disregard of the  
24          public's safety. The public's safety has been benefitted  
25          by this drug. That is the final irony. The public safety

1 is what has benefitted and benefitted by the marketing of  
2 this drug, exactly as Dr. Kahn had hoped it would be.

3 Thank you, Your Honor.

4 THE COURT: Thank you, Mr. Dames.

5 Did you have anything else, Mr. Goldser?

6 MR. GOLDSER: Briefly, Your Honor. I once again  
7 thank Mr. Dames for a preview of his closing argument to  
8 the jury, but as I said in my opening remarks, what he says  
9 about the evidence in that fashion this Court must  
10 disregard.

11 In reaching a determination about punitive  
12 damages, the Court makes no credibility awards, does not  
13 consider any challenge by cross-examination or otherwise to  
14 plaintiffs' proof. So the spin that Mr. Dames puts on it  
15 has nothing to do with this Court's determination at this  
16 point in time. This Court has to decide whether from the  
17 plaintiffs' evidence there is a prima facie showing of  
18 deliberate disregard.

19 I could go on for a long time responding seriatim  
20 to each of the points that Mr. Dames makes. Let me pick up  
21 a couple of them. For example, he says, tendon ruptures  
22 were used as a measure because they were the most  
23 objectively verifiable test. Then why was it when the  
24 algorithm was completed that there were far more Levaquin  
25 tendon ruptures discarded as nonviable cases than Cipro

1 tendon ruptures?

2           Even when you get to the level of tendon rupture  
3 as they claim was the gold standard, their algorithm  
4 resulted in a manipulation that substantially threw out  
5 more Levaquin cases than Cipro cases. That was part of the  
6 manipulation that was involved.

7           Mr. Dames says, and the Medicare database was  
8 added. Indeed it was. There were three drafts of the  
9 study that were promulgated over time. The Medicare data  
10 was added in the second draft. The problem is, it was the  
11 first draft that was sent to the European agencies, and it  
12 was the first draft that caused the European agencies to  
13 back down.

14           That first draft did not have the Medicare data  
15 in it, and so the fact that the Medicare data was in the  
16 second draft did nothing to influence the European agencies  
17 to back down from their proposed warning. Mr. Dames says  
18 there are children in the database, and that was just  
19 normal and it doesn't matter, but you've got to think about  
20 what the impact of the children being in the database was.

21           They had no tendon ruptures because they weren't  
22 taking Levaquin. So if you have children in the database  
23 and you have got 100 people in the database as a result of  
24 the children being in the database and there is one tendon  
25 rupture in the adults, that's a 1 in 100 rate.

1           But if you throw out the children and let's say  
2           90 percent of them were children, and obviously I'm using  
3           an extreme example, but you only have 10 adults in the  
4           database and one of those adults has a tendon rupture, you  
5           have a rate of 1 in 10. That's 10 percent. Children in  
6           the database mattered substantially because they skewed the  
7           numbers. It's not quite as easy as Mr. Dames would like to  
8           suggest.

9           I'm intrigued by the extensive argument that  
10          Mr. Dames makes about how no foreign regulatory authority  
11          took any legal action to change the label, and yet time  
12          after time after time in oral argument and in briefs in  
13          this court, defense has said you can't consider what the  
14          legal actions were that were taken by foreign agencies.  
15          We're not allowed to do that, they say, with Dr. Blume and  
16          her evidence.

17          There is a motion, the *Daubert* motions, their  
18          *Daubert* motion specifically addresses that. We can't do  
19          that, so well, why can they? Either those legal actions  
20          taken by the regulatory authorities are in or they're out.  
21          Not good for the goose, not good for the gander. It's our  
22          burden to show you based on our evidence and our spin of  
23          that evidence that a jury could find that punitive damages  
24          are warranted.

25          I understand Mr. Dames's spin. He has given us

1 that from the get-go. I hardly agree with it, but that  
2 doesn't matter for today. Mr. Saul had a comment he wanted  
3 to make.

4 THE COURT: Go ahead, Mr. Saul.

5 MR. SAUL: Very briefly, Your Honor, I must say I  
6 was somewhat disappointed in Mr. Dames and some of the  
7 things he said, particularly about the issue of destruction  
8 of the documents. He said that they were somehow destroyed  
9 in an office move.

10 It is just one minute of testimony of Dr. Seeger.  
11 I'm taking the examination. And who made the decision to  
12 destroy them? Mr. Saul.

13 I don't recall exactly, but it could have been  
14 one of a couple of scenarios. Either somebody asked me if  
15 I could, if these could be discarded and I said yes, or  
16 it's possible that the default was to get rid of things  
17 unless somebody stepped forward, and I did not step forward  
18 to not discard them.

19 Everything was discarded unless someone said save  
20 it?

21 That's right.

22 And it was your responsibility to determine in  
23 this particular project what was saved and what was thrown  
24 away?

25 That was a possible scenario.

1           What?

2           That was a possible scenario. Yes.

3           That was a question. Was it or was it not your  
4 decision as the project manager in this particular project  
5 to save or destroy documents?

6           It was my decision, and I followed one of those  
7 two scenarios that I laid out.

8           What Mr. Dames said was not what the testimony  
9 was. Thank you.

10          THE COURT: Mr. Robinson?

11          MR. ROBINSON: Thank you, Your Honor. Bill  
12 Robinson for the defendants. I will be brief. First with  
13 respect to Mr. Goldser's comments about the fact that the  
14 algorithm used in the Seeger study found more ciprofloxacin  
15 cases than levofloxacin cases, he did not tell you  
16 Dr. Seeger's answer when he was asked that at the  
17 deposition.

18          In fact, Dr. Seeger did a separate post hoc study  
19 of that issue, and it's very clear that doctors were  
20 misdiagnosing tendon ruptures in Levaquin patients, and  
21 that's in the published article. Basically that's why  
22 there were more ciprofloxacin cases. There was a  
23 diagnostic bias found in the study against levofloxacin and  
24 tendon ruptures.

25          Secondly, with respect to the Medicare database,

1 the testimony is pretty straightforward. The Medicare  
2 population was not available for the database when the  
3 initial protocols were done. As soon as it was available,  
4 it was added. The Medicare patients were included in the  
5 final study results and in the published paper results and  
6 in the results given to all the regulators.

7 The question of the children in the database,  
8 Dr. Seeger's comment to that was why would you exclude  
9 children from the database? You're looking at a study of  
10 the use of levofloxacin. Some doctors do use levofloxacin  
11 off label use for children. In fact, you're probably going  
12 to hear a lot about some of the studies done with children  
13 in the course of the trial.

14 As it turned out, there were no cases in the  
15 study of any children with an Achilles tendon rupture that  
16 were included in the data. That doesn't skew the data, the  
17 fact that they found no cases, because it's a case control  
18 study. You're comparing to controls. You're not looking  
19 at total numbers of cases in that sense.

20 In terms of the destruction of documents,  
21 Mr. Saul has referred to that on a couple of occasions  
22 here. Just for the record to be very clear what was  
23 destroyed, Dr. Seeger selected 328 random sample potential  
24 cases of Achilles tendon rupture, sent people out to get  
25 records, do abstraction forms. Those are the records that

1 were destroyed.

2 It's important to note Dr. Seeger was asked a  
3 question, well, could you reproduce this study without  
4 those records. He said, yes, you could. It would take  
5 some time and effort and money, but you could do that  
6 because they still have the code numbers for all those  
7 patients.

8 Those records have nothing to do with the final  
9 case selection process which was done by the algorithm, and  
10 I will just note, Your Honor, the algorithm was blinded to  
11 all fluoroquinolone exposure of any type, all antibiotic  
12 exposure. So the final computer program that picked the  
13 cases that were the cases included in the data analysis for  
14 the study was totally blinded to drug exposure, which  
15 fluoroquinolone, which antibiotic or whether any was used.  
16 It wasn't there.

17 Thank you.

18 THE COURT: Thank you, Mr. Robinson. Okay.  
19 Thank you, Counsel. The Court will take the motion under  
20 advisement and issue a written order quickly. Let's take a  
21 five-minute break before the other motions.

22 THE CLERK: All rise.

23 **(Recess taken.)**

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**(In open court.)**

THE COURT: You may be seated. Okay. You may be seated. Okay. Let's take the other motions.

Ms. Van Steenburgh.

MS. VAN STEENBURGH: Your Honor. We're going to narrow the focus a little bit and look just at the complaint in the Schedin case, although we have included as our motion the other bellwether cases. Before I begin, Mr. McCormick informed me prior to my approaching the podium here that the plaintiffs are going to withdraw their claims on the Deceptive Trade Practices Act. That happens to be embedded in Count Number VI. There are two claims in there, but they will withdraw that one, so I will just restrict my comments.

MR. MCCORMICK: That's correct, Your Honor. We decided from the seven complaints that are at issue, six complaints that are at issue in this motion. Thank you, Your Honor.

THE COURT: Very well. Go ahead.

MS. VAN STEENBURGH: So we're moving today for motion on judgment on the pleadings in partial. There are three claims we're not moving on, strict liability, negligence and fraud. But there are seven causes of action that we believe are subject to dismissal, and they can be grouped into three areas: Consumer fraud, the warranty

1 claims and the unjust enrichment claim.

2 Each of those is deficient in terms of its  
3 pleading and are subject to dismissal. What I would like  
4 to do is turn to the consumer fraud claims initially. That  
5 would be Counts VI, VII, VIII and IX. I'm not going to  
6 spend really any time on Count VII, that's the handicapped  
7 and elderly provision, and that's derivative of the other  
8 consumer fraud statutes.

9 But as to the consumer fraud statutes in  
10 themselves, the basis of the motion is that the plaintiffs  
11 cannot show any public benefit. As the Court well knows,  
12 there is no private cause of action under those statutes,  
13 and in order to bring a claim, a plaintiff has to invoke  
14 Section 8.31 under the Minnesota Statutes, and the purpose  
15 of that is to allow a private litigant to stand in the  
16 shoes of the Attorney General.

17 And the purpose of the statute is to expand  
18 efforts to stop or prevent fraudulent business practices.  
19 Well, just as the Attorney General would have to do that  
20 for the benefit of the public, a private litigant has to  
21 show that in fact they are operating to benefit the public  
22 when they bring such a cause of action.

23 Now the plaintiffs have taken the position here  
24 that as long as their complaint alleges deceptive trade  
25 practices aimed at the public at large, they have satisfied

1 the public benefit requirement under the case law and the  
2 statutes. They rely on the *Collins versus Minnesota School*  
3 *of Business* case, and that case cannot be read so narrowly.

4 There was a narrow issue in that case involving  
5 District Court interpretation of a public benefit saying  
6 that maybe the number of plaintiffs was too small, and the  
7 Court said no, you need to focus more on what the  
8 representation was that it was a larger, it was made to the  
9 public.

10 But really the *Collins* case is consistent with  
11 the other case law having to do with the public benefit  
12 because the real issue is, what's the remedy and whether  
13 the lawsuit would change the behavior of defendant, whether  
14 you're going to stop deceptive trade practices or not. The  
15 *Collins* case, the minute the lawsuit was started, the  
16 television ads and the presentations that the Minnesota  
17 School of Business were presenting in order to attract  
18 students stopped immediately, and so the kind of behavior  
19 was immediately stopped by the lawsuit.

20 This case is very different. Mr. Schedin has  
21 brought an action. He brought an action three years after  
22 he took Levaquin. This is a classic products liability  
23 action. It involves products liability negligence, and the  
24 remedy is an individual remedy.

25 There are a series of cases, Judge Montgomery and

1 Magistrate Judge Erickson have rendered decisions in which  
2 they looked at that remedy, and when it's an exclusively  
3 individual remedy, they have held that that does not accrue  
4 to the public benefit. Mr. Schedin is seeking damages for  
5 himself, pain and suffering, past medical expenses, future  
6 expenses. Those are not for the public benefit.

7 If you also look at the representation, the issue  
8 in this case, and you look at the cases that look at that,  
9 for example, this case, the *Swenson* case, the horrible  
10 security case involving ADT Securities, and also Judge  
11 Magnuson on the *Tuttle* case, the issues there were, what  
12 are those representations?

13 What is happening? Are those still out there?  
14 Are they continuing? Is there something about this lawsuit  
15 that is going to change behavior? If you look at this  
16 case, this case involves the 2002 with the minor  
17 modification, the 2004 label. That label does not exist  
18 anymore. That label is not out in the public domain.  
19 There is nothing about that label.

20 We are litigating something in the past. It's  
21 like the childproof lighters in *Pecarina* that Judge  
22 Montgomery said they're not on the market. They're not  
23 going to change behavior. In *Tuttle* Judge Magnuson said  
24 that the plaintiff wanted to bring consumer fraud claims  
25 because she wanted to warn other consumers about smokeless

1 tobacco. The label had already been put on by the FDA.

2 The whole situation here is again, the claim is,  
3 was the label in 2004 adequate, and the plaintiff has lots  
4 of arguments as to why it wasn't. There wasn't sufficient  
5 information. We didn't send out dear doctor letters. It  
6 was confusing. In the end, if there is ever a verdict  
7 form, it's going to say was the label inadequate. It's not  
8 going to do anything about this label because that label  
9 doesn't exist anymore.

10 So the Consumer Fraud Act claims just do not  
11 apply because there is no public benefit by virtue of those  
12 claims in this lawsuit.

13 Turning now to the warranty claims, I'm going to  
14 just spend a brief moment, Your Honor, because I think  
15 those are pretty straightforward. They're in Count III.  
16 There is an implied breach of warranty claim. This Court  
17 has addressed that issue before. Strict liability in  
18 Minnesota preempts an implied warranty of merchantability,  
19 and so as long as there is a strict liability claim, there  
20 cannot be an implied warranty claim.

21 With respect to breach of express warranty, I'm  
22 amazed. There was lots of rhetoric in the plaintiffs'  
23 brief about how Minnesota recognizes an express warranty  
24 claim. Great. That's true. But the question is, what is  
25 that warranty that is the basis of the claim in this

1 lawsuit, and you look at page 19 of the plaintiffs' brief,  
2 they don't explain that at all.

3 They just fuss it up. They don't identify  
4 anything with respect to what that warranty is, and if you  
5 look at the complaint, paragraph 136 of their complaint  
6 where that warranty should be, all it says is that it  
7 wasn't safe. That's no different than an implied warranty,  
8 safe for its intended purpose.

9 So it's duplicative of the implied warranty.  
10 That one should also be dismissed. If it's an implied  
11 warranty, it's preempted under Minnesota law relative to  
12 strict liability. Finally, with respect to Count X, the  
13 unjust enrichment, I think that has been well briefed as  
14 well. As long as there is an adequate remedy at law, the  
15 equitable claims do not stand, and there are cases that  
16 have been, that so hold.

17 The plaintiffs do cite to a case by Judge Davis  
18 where he allowed an unjust enrichment claim, but if the  
19 Court notes those facts, there were lots of equitable  
20 claims in that set of facts. This was not in an  
21 alternative. Here there are plenty of adequate remedies at  
22 law under the strict liability, the negligence, the fraud  
23 claims.

24 The unjust enrichment claim is an equitable claim  
25 that should be dismissed. If there is nothing further?

1           THE COURT: Let me ask you one question,  
2 Ms. Van Steenburgh.

3           MS. VAN STEENBURGH: Yeah.

4           THE COURT: Back to the question about the public  
5 benefit.

6           MS. VAN STEENBURGH: Mm-hmm.

7           THE COURT: Do you think there is anything to an  
8 argument that although this is an action that is seeking  
9 damages that are personal to Mr. Schedin, and most of these  
10 cases do relate to that, is there an argument that because  
11 particularly his case is coming first as a bellwether trial  
12 in an MDL it affects a lot of potential future plaintiffs  
13 or current plaintiffs in other cases that that can somehow  
14 confer a public benefit by participating in the trial in  
15 that way?

16           MS. VAN STEENBURGH: I don't think so for a  
17 couple of reasons. Every single one of these cases really  
18 is an individual case. They just happen to be collected  
19 here for pretrial discovery as part of an MDL. All of  
20 these cases may involve different labels.

21           Mr. Schedin's case involves a 2004 label, so  
22 there may be one that involves a 2002. We have got a 2007.  
23 We have got a 2008, so you can't necessarily say that  
24 Mr. Schedin's case involving this particular label, which  
25 does not exist anymore, could somehow confer a public

1 benefit with respect to any of those others. The adequacy  
2 of any of those others in any of those cases has to be  
3 litigated separately.

4 THE COURT: Thank you.

5 MS. VAN STEENBURGH: Yes.

6 MR. MCCORMICK: Almost afternoon, Your Honor.  
7 Good morning. Still there.

8 THE COURT: You're close.

9 MR. MCCORMICK: Hopefully I will be done before  
10 afternoon, Your Honor. Your Honor, your last question I  
11 think goes to the heart of the public benefit issue, which  
12 is where does the public benefit begin to run or when does  
13 a public benefit stop running for an individual bringing a  
14 claim under these Minnesota statutes?

15 For every *Pecarina* case and every *Berczyk* case  
16 that Ms. Van Steenburgh can cite to you, I can cite your  
17 *ADT* case, which you know better than I do. I can cite to  
18 you the *Weigand versus Walser* case, which is a Minnesota  
19 state court case. I can cite to you the *Kinetic versus*  
20 *Medtronic*, all those cases where conduct may have stopped  
21 during the course of the lawsuit.

22 The public benefit still was seen, and there  
23 still was an enforceable case underneath the consumer fraud  
24 statutes using the Private Attorney General Act.

25 THE COURT: What about this argument that simply

1 bringing these claims now inside of an MDL with a potential  
2 impact on others? I mean is that a theory that would  
3 support a public benefit? Do you know of any cases that  
4 addressed the issue in that way?

5 MR. MCCORMICK: I do not, Your Honor, but I think  
6 if you go back and look -- I spent more time on Minnesota  
7 law in the past three months than I ever thought I would.  
8 If you go back and look at legislative reading and you go  
9 back and you look at the *Ly versus Nystrom* case and what  
10 led from that, I think that the way the defendants would  
11 have you read the public benefit is to basically shut down  
12 the consumer fraud statutes to almost any individual trying  
13 to bring, seek redress under those cases.

14 So I think that while there is not a case  
15 specifically on point, I think if you look at the line of  
16 cases that we have versus the line of cases that the  
17 defendants would rely on, I believe that this case is  
18 closer to the *Collins* line than it is to the other line of  
19 cases.

20 THE COURT: Recognizing that there is not  
21 injunctive relief sought and I think that the public  
22 benefit issue is more complicated than just injunctive  
23 relief versus personal damages, the current label, the  
24 November '08 label which I have a copy here in front of me,  
25 is that an adequate label?

1           MR. MCCORMICK: Your Honor, we would argue it's  
2 not an adequate label.

3           THE COURT: Does that affect the public benefit  
4 issue?

5           MR. MCCORMICK: I would believe it would. If,  
6 for example, in your *ADT* case if that is the issue, we  
7 should be able to amend the complaint to add the inadequacy  
8 of the November 2008 label, but looking back at the  
9 November 2004 label, Mr. Schedin's complaint was filed  
10 before the November 2008 label, but our argument all along  
11 and always will be, I believe, that the new label is not  
12 adequate, either.

13          THE COURT: Okay.

14          MR. MCCORMICK: Your Honor, I think I can be as  
15 brief with the implied warranty and the express warranty  
16 claims as defendant was. All of the cases that the  
17 defendants rely on for their citations to the express  
18 warranty -- well, let me stay with the breach of implied  
19 warranty.

20                 At this point dismissing that claim on a motion  
21 for judgment on the pleadings is premature. We should be  
22 able to present that case to the jury. Then in a jury  
23 instruction if you decide at the end of the trial whether  
24 we're going to present it or if you say the jury  
25 instructions are going to be confusing, then we withdraw

1 that case.

2 Doing it right now before we get to the case, the  
3 actual trial, would be premature. All of the cases that  
4 they rely on are distributor cases. This is a case that  
5 involves a manufacturer. The express warranty claim is,  
6 again, I believe that their argument is misplaced here.

7 This is a motion for judgment on the pleading.  
8 If they felt like our express warranty does  
9 not expressly -- what we're complaining about is not in the  
10 complaint, they should have filed a motion for summary  
11 judgment and said your evidence isn't there.

12 At this point we have taken discovery for two and  
13 a half years. There is discovery that we could point to,  
14 express warranties over and over amongst the defendants'  
15 labels, the representations they have made to physicians,  
16 the detailing that they hand out. So --

17 THE COURT: But do we have evidence in these  
18 individual, what are we dealing with, five separate motions  
19 here?

20 MR. MCCORMICK: Six.

21 THE COURT: Six, that express warranties were  
22 made to patients or their doctors in these cases? Is there  
23 anything that has developed?

24 MR. MCCORMICK: Your Honor, I think under the  
25 Minnesota law, a general statement made by the company that

1 may have made it down to the physician or the patient is  
2 enough, but I don't know the specifics of these cases, but  
3 Mr. Goldser could better answer that question, Your Honor.

4 THE COURT: That's fine.

5 MR. MCCORMICK: As to the unjust enrichment  
6 claim, Your Honor, it is similar to our breach of implied  
7 warranty claim which is that this is a premature motion.  
8 While we have adequate theories of law, the unjust  
9 enrichment claim is not ready to be dismissed. We should  
10 be able to try a case like that.

11 If at the end of the trial we decide that there  
12 is no evidence or if you decide that the case then is  
13 unworthy, we should drop it out then before you give us  
14 your jury instruction.

15 THE COURT: On the implied warranty claim, when  
16 do you choose between that and strict liability?

17 MR. MCCORMICK: I would think when we have a  
18 charging conference, Your Honor, and you say what cases are  
19 you going to charge the jury on, and we say this or this.

20 THE COURT: We can probably make that clear to a  
21 jury at the end of the case, but it may get confusing  
22 during the trial.

23 MR. MCCORMICK: I would think that we would be  
24 able to provide evidence on both claims to the jury. To be  
25 honest, I think probably the same elements would go in, so

1 I don't know if the jury would understand until they  
2 receive two different instructions on the same elements.

3 Thank you, Your Honor.

4 THE COURT: Thank you.

5 MR. GOLDSER: May I, Your Honor?

6 THE COURT: Sure, Mr. Goldser.

7 MR. GOLDSER: I remember Professor Marshall from  
8 the University law school, dearly departed, I don't know if  
9 you had any experiences with him.

10 THE COURT: Oh, yes.

11 MR. GOLDSER: Wonderful man. When we were  
12 talking about the purpose, the public policy behind tort  
13 law, I hope this is going to work, that one of the public  
14 policies behind tort law was to change behavior of the  
15 defendant, and so I think you are exactly right when you  
16 say it's more complicated than simply whether or not there  
17 is injunctive relief.

18 Tort damages, tort cases for damages can get you  
19 there. I spent a long time earlier this morning talking  
20 about one of the theories of liability, and that is that  
21 Levaquin is worse than other fluoroquinolones in terms of  
22 comparative tendon toxicity. That is not in the warning.  
23 Never has been. Defendant denies it to this day. It's  
24 certainly not in the black box warning.

25 That, if we can convince a jury that there is

1 inadequate warning on that, is in fact a public benefit.  
2 Of course one would hope that defendant would learn from  
3 the tort decision on an individual remedy case that they  
4 need to change their warning to address the question of the  
5 comparative tendon toxicity of Levaquin versus other  
6 fluoroquinolones, which dovetails exactly into the express  
7 warranty issue.

8 And what I have up in front of you at the moment  
9 are the call notes that were provided to us by defendant  
10 where the defendants' sales representatives called on  
11 Dr. Beecher, and the one that you see right in front of  
12 you, and it actually scrolls up a little bit, this page, as  
13 you can see is July 2, 2002, it's Dr. Beecher.

14 Monica Sadar over here is the name of the sales  
15 representative, and when she is done with the call, she  
16 writes in this box down here what occurred in the call.  
17 And you can see that she described to Dr. Beecher on July  
18 2, 2002, the safety of Levaquin versus other quinolones,  
19 versus Augmentin as well, and I don't understand what that  
20 last tag phrase is IN SIN, but she was there talking to  
21 Dr. Beecher that day about how Levaquin compares in safety  
22 to other fluoroquinolones.

23 I can promise you she didn't say to Dr. Beecher,  
24 well, you know, Levaquin is worse than other  
25 fluoroquinolones in terms of the tendon toxicity. Quite

1 the opposite. This call might suggest that it is in fact  
2 safer than other fluoroquinolones, which is a  
3 misrepresentation, and it's also an express warranty.

4 I can find for you several other references to  
5 descriptions of tolerability and safety. You can see that  
6 over on the right. This call note I believe was created on  
7 the top of the page July 12, 2002.

8 There were several others that look very similar  
9 that talked about safety as Monica Sadar or other sales  
10 reps referenced specifically to Dr. Beecher, the doctor in  
11 this case. We have not only an express warranty just  
12 generally out there, we have got a specific express  
13 warranty that was made to Dr. Beecher that we can see in  
14 the call notes.

15 Thank you.

16 MR. SAUL: Just one thing, Your Honor?

17 MS. VAN STEENBURGH: I'm getting triple teamed  
18 here. Seems unfair.

19 THE COURT: Go ahead, Mr. Saul.

20 MR. SAUL: 60 seconds.

21 THE COURT: We can give Mr. Dames and  
22 Mr. Robinson a chance.

23 Go ahead, Mr. Saul.

24 MR. SAUL: During depositions I specifically  
25 asked the defendants' experts as well as their employees,

1 did they agree or disagree with the black box warning,  
2 which is now in effect, and across the board, they either  
3 disagree with it in whole or in part.

4 So in terms of the public benefit, you have it  
5 there in testimony throughout the litigation.

6 THE COURT: Thank you.

7 Ms. Van Steenburgh?

8 MS. VAN STEENBURGH: Well, first, let me bring us  
9 back to the fact that we're here for a motion for judgment  
10 on the pleadings. Mr. Goldser has now just introduced a  
11 bunch of evidence that I wasn't aware that those were the  
12 express warranties. We looked at the complaint. The  
13 complaint says nothing. Paragraph 136 just says including  
14 plaintiff and physicians that Levaquin had been shown by  
15 scientific study to be safe for its intended use.

16 Their brief in response when we said there isn't  
17 an express warranty, as to express warranties, the various  
18 complaints make it clear with factual affirmations and  
19 product descriptions of Levaquin that form the basis of  
20 additional express warranties.

21 There is never any representation as to what  
22 warranty, where, who or what, other than it's safe, and  
23 even as Mr. Goldser said, the warranty that was given  
24 Dr. Beecher is, it was safe. That's an implied warranty.  
25 So there is nothing different about the express warranty

1 claim than there is the implied warranty claim.

2 Now, stepping back to that, what I'm hearing is,  
3 they don't want to make a decision about whether they're  
4 going to stick with their strict liability claim now or  
5 later. If they get rid of the strict liability claim,  
6 negligence merges in with the implied warranty, so that  
7 goes away anyway at trial.

8 So whether we get rid of it now or later it is  
9 not going to make any difference if they decide to drop  
10 their strict liability claims. Strict liability, and  
11 negligence is equal to the implied warranty, and under  
12 Minnesota law, you have to get rid of the implied warranty  
13 claim. So the decision is actually subject now. Strict  
14 liability as long as it stays in the complaint preempts  
15 implied warranty.

16 The final thing I wanted to say is, there seems  
17 to be some confusion about this issue of the public  
18 benefit. The question was, do the plaintiffs believe that  
19 the 2008 label is adequate? That isn't the subject of  
20 Mr. Schedin's lawsuit, nor any of the other bellwether  
21 plaintiffs.

22 The adequacy of the 2008 label is not at issue.  
23 The issue is the adequacy of the 2004 label, and that's  
24 what is going to be litigated in this case, and that label  
25 doesn't exist.

1           Now I hear Mr. Goldser saying, well, they still  
2           don't have two times endotoxic in the future label. Well,  
3           is that the only thing that is ever going to be litigated  
4           as part of the 2004 label? No. They have identified all  
5           kinds of deficiencies.

6           There is nothing that -- about the 2008 label  
7           that somehow can be brought back to the 2004 label, and if  
8           you look at *Pecarina*, you look at the *Tuttle* case, and it's  
9           distinguished from the *Swenson* case because in that case it  
10          was unclear whether there was national sales literature and  
11          installation literature still out there such that the  
12          impact of the lawsuit might impact the behavior. The 2004  
13          label doesn't exist.

14          It is not going to have an effect. It is more  
15          like *Tuttle* where the label has changed, and now we're  
16          litigating something in the past. And whether Mr. Schedin  
17          is entitled to damages for past medical expenses, pain and  
18          suffering as a result of the alleged inadequacy of the  
19          label is the issue before the Court.

20          There is no public benefit with respect to that  
21          label, and thus there can be no consumer fraud claims.  
22          Thank you, Your Honor.

23                 THE COURT: Thank you, Ms. Van Steenburgh. Do  
24                 you want some backup?

25                 MR. DAMES: She apparently doesn't need it.

1 MR. ROBINSON: We have our batting helmets.

2 THE COURT: Okay. Did you have anything else,  
3 Mr. McCormick?

4 MR. MCCORMICK: Your Honor, just one quick thing,  
5 and it brings me back to the express warranty, which is at  
6 this point in time a motion for judgment on the pleadings  
7 as opposed to a Rule 12 motion. If they felt like our  
8 express warranties were not there and not in the complaint,  
9 they should have brought a motion for summary judgment to  
10 have that opportunity, and they didn't do it.

11 As to the public benefit argument, I think my  
12 argument stands in that if you would read the public  
13 benefit as narrowly as defendants would have you do in an  
14 MDL setting, it would defeat the purpose of an MDL and  
15 setting law and following law and setting a group going  
16 forward for the rest of these cases.

17 Thank you, Your Honor.

18 MR. GOLDSER: So the records are clear, we move  
19 to amend the complaint to incorporate the express  
20 warranties set forth in the call notes that I described to  
21 you.

22 THE COURT: Speaking of the call notes,  
23 Mr. Goldser, where in the record is what you showed us  
24 there? Can you cite to the record so that we can look that  
25 up?

1           MR. GOLDSER: I don't believe it's in the record.  
2           Because this was a judgment on the pleadings, we didn't  
3           submit any evidence. I'm happy to send them to you if you  
4           would like.

5           THE COURT: I see. Okay. Anything else on the  
6           motions? Okay. Very well. Okay. Let's talk a little bit  
7           about scheduling. We have, I believe, I believe it's next  
8           week, Wednesday, the *Daubert* motions, the 6th? We have  
9           inquired about the advisability of splitting them up  
10          somehow. I am of a couple of minds about that. I thought  
11          I would raise that anyway.

12          I guess it depends in part on the length of  
13          arguments that you wish to do on the *Daubert* motions. If  
14          it's lengthy argument involving all of them, then -- I want  
15          to make sure. I've got a trial going on next week. I want  
16          to make sure I have enough time to prepare for all of them  
17          and to be able to prepare for arguments.

18          What's anticipated right now? Maybe each of you  
19          have thoughts on this.

20          MR. GOLDSER: I'm not sure that we have gone into  
21          a great deal of detail yet about what we want to argue and  
22          how we want to argue it. I have the concern about the  
23          longer we go before we get a ruling, the closer we are to  
24          trial, of course.

25          But I like to with, with due humility and

1 respect, suggest a possible solution. It may impose a  
2 greater burden on the Court, however. There is a procedure  
3 that is used in California courts, both state and federal,  
4 where the Court issues what is called a tentative ruling.  
5 I don't know if you're familiar with that.

6 I have experienced it a few times. It's pretty  
7 wonderful from a litigant's perspective. The Court  
8 actually issues a proposed order, and the litigants get it  
9 when they walk into court that morning.

10 THE COURT: Judge Renner did something like that  
11 on a regular basis. He would announce his tentative  
12 decision and ask lawyers to tell him where he was wrong.  
13 He was rarely wrong.

14 MR. GOLDSER: I find that to be true certainly as  
15 well when I have been in California, but from my  
16 perspective it's really wonderful. It cuts down the amount  
17 of time for the argument, and it focuses the argument. Of  
18 course, it puts a tremendous burden on the Court to have  
19 tentative rulings done.

20 One court, I wish I could recall who it was,  
21 handed out a list of questions, as opposed to what the  
22 tentative ruling would be, so that the arguments could be  
23 really focused. I went on at great length because I wanted  
24 to tell you the story. It was the first time I think we  
25 have had the chance. You have now seen it, and you have

1 read a lot about it in the *Daubert* briefs, so I don't know  
2 that we have that great need to go there.

3 I want to focus on what you need to know to make  
4 those decisions. If you can help us with that, I think we  
5 can get it done in one day.

6 MR. DAMES: We don't have an objection to having  
7 one day to hear all the motions. I think that really is  
8 going to be your calendar for the preparation time if you  
9 feel that you need to do --

10 THE COURT: What are you anticipating for the  
11 argument time?

12 MR. DAMES: You know, we haven't discussed it,  
13 Your Honor, but at some point the issues, I mean, clearly  
14 the first arguments are going to be longer than the later  
15 arguments, I suspect. The Seeger lay argument will  
16 probably be one of the longer arguments. The --

17 We have the Waymack/Blume arguments will probably  
18 be quite significant, and I should tell the Court that  
19 we're going to have John Winter, who is an attorney with  
20 Patterson Belknap, come and argue those motions.

21 THE COURT: Mm-hmm.

22 MR. DAMES: It's hard to say, but none of them  
23 will be particularly short.

24 MR. ROBINSON: Your Honor, if the Court will  
25 entertain possibilities here, we could do as much as we

1       could on the 6th and then perhaps have another date on the  
2       13th if that's convenient for the Court as suggested to  
3       finish up if we need it.

4               THE COURT: Well, I mean, we will issue the order  
5       just as quickly as possible. It will be, obviously we know  
6       the trial is coming up, and it goes to the top of the list,  
7       so, you know, maybe that is the best way to proceed.

8               If I can give the parties some direction in  
9       advance, I will do so, but I'm not promising anything right  
10      now. I'm starting this other trial on Monday, and that  
11      will involve a lot of -- it's a bench trial, too. So --  
12      but we can --

13              Go ahead.

14              MR. DAMES: I think that for some of the motions,  
15      I've had experience in California with the, with that  
16      procedure. It isn't a bad procedure to utilize if you  
17      think the oral argument isn't going to clarify things or if  
18      oral argument is going to have a substantial benefit.

19              I think on the *Daubert* motions, oral argument  
20      probably will have a substantial benefit so that, I mean,  
21      because a lot of arguments foreclose with that kind of a  
22      preliminary decision in practice, and I just think that it  
23      might be the least appropriate method, time to use that  
24      procedure if you do it with the *Daubert* motions.

25              THE COURT: Well, go ahead, Mr. Saul.

1           MR. SAUL: Your Honor, we suggest, plaintiffs  
2 suggest you do one plaintiff, one defendant, back and forth  
3 between the motions.

4           MR. ROBINSON: That's fine with us if the Court  
5 wants to set some kind of schedule.

6           THE COURT: We'll let you know. We'll try to get  
7 to that, you know, a day or two in advance so you know  
8 exactly how we are going to proceed, and I think the  
9 suggestion, we'll do what we can on the 6th, and if we  
10 can't get it all done, we'll just schedule another day  
11 shortly thereafter.

12           MR. ROBINSON: Your Honor, originally when we had  
13 talked about the schedule, we had reserved October 7th. I  
14 take it that is not going to happen now, and I just want to  
15 be clear about that.

16           THE COURT: Well, let's look here and see what we  
17 have got. I think we should probably continue to hold that  
18 for now, but I do have this other trial. It's just the  
19 other trial. That's all I have going on other than a  
20 sentencing.

21           I do have time available that day if we need to  
22 spill over. So I think let's hold it for now. Okay?

23           MR. ROBINSON: Yes, sir.

24           THE COURT: Okay. Anything else we need to  
25 discuss today?

1 MR. GOLDSER: I don't think so, Your Honor.

2 THE COURT: Okay. Very good.

3 MR. DAMES: Thank you, Your Honor.

4 MR. ROBINSON: Thank you, Your Honor.

5 THE COURT: The Court is in recess. Thanks for  
6 the arguments today.

7 THE CLERK: All rise.

8 **(Court was adjourned.)**

9 \* \* \*

10 I, Kristine Mousseau, certify that the foregoing  
11 is a correct transcript from the record of proceedings in  
12 the above-entitled matter.

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16 Certified by: s/ Kristine Mousseau, CRR-RPR  
17 Kristine Mousseau, CRR-RPR

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